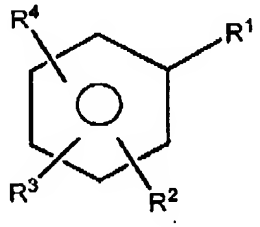
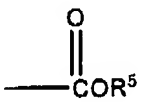
KCC 4749.2
K.C. 16,858.2
PATENT

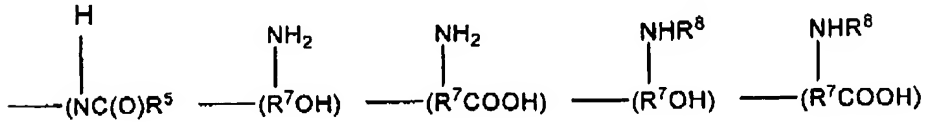
1. Rejection of Claims 1, 11, and 14-20 Under 35 U.S.C. §103(a)

Reconsideration is requested of the rejection of claims 1, 11, and 14-20 under 35 U.S.C. §103(a) as being unpatentable over DE 1204777 in view of D'Augustine, et al. (U.S. 6,416,779).

Claim 1 is directed to an exoprotein inhibitor for inhibiting production of exoproteins from Gram positive bacteria in and around the vagina. The exoprotein inhibitor comprises a non-absorbent substrate for insertion into a vagina being selected from the group consisting of a non-absorbent incontinence device, a barrier birth control device, a tampon applicator, and a douche. The non-absorbent substrate has deposited thereon an effective amount of a first active ingredient having the general formula:



wherein R^1 is selected from the group consisting of H,  $-OR^5$, $-R^6C(O)H$, $-R^6OH$, $-R^6COOH$, $-OR^6OH$, $-OR^6COOH$, $-C(O)NH_2$,



and NH_2 and salts thereof; R^5 is a monovalent saturated or unsaturated aliphatic hydrocarbyl moiety; R^6 is a divalent saturated or unsaturated aliphatic hydrocarbyl moiety; R^7 is a trivalent saturated or unsaturated aliphatic hydrocarbyl moiety; R^8 is a monovalent substituted or unsubstituted saturated or unsaturated aliphatic hydrocarbyl moiety which may or may not be interrupted with hetero atoms; R^2, R^3, and R^4 are independently selected from the group consisting of H, OH, COOH, and $-C(O)R^9$; R^9 is hydrogen or a monovalent saturated or unsaturated aliphatic hydrocarbyl moiety. The first active ingredient is effective in inhibiting the production of exoprotein from Gram positive bacteria.

DE 1204777 ('777) discloses a method of increasing the bactericidal action of hexachlorophene. The method includes combining hexachlorophene with 1% (by weight) to 95% (by weight) benzoic acid, aniline, or benzamide. Specifically, '777 discloses that the addition of benzamide, in a concentration of from 50% (by weight of the mixture with hexachlorophene) to 91% (by weight of the mixture with hexachlorophene), increased the germicidal activity against Staphylococcus aureus by 37% to 100% and at the same time, accelerated the killing action. Additionally, benzoic acid and aniline showed a synergistic bactericidal effect when combined with hexachlorophene.

As noted by the Office in the Office action dated November 28, 2005, '777 fails to disclose a non-absorbent substrate for insertion into the vagina being selected from the group consisting of a non-absorbent incontinence device, a barrier birth control device, a tampon applicator, and a douche. In an

attempt to find each and every element of claim 1 as required by the M.P.E.P. for a determination of *prima facie* obviousness, the Office cites the D'Augustine et al. reference for combination with '777.

D' Augustine et al. disclose devices, methods, and compositions for treating vaginal fungal, bacterial, viral, and parasitic infections by intravaginal or transvaginal administration of therapeutic and/or palliative antifungal, antibacterial, antiviral or parasiticidal drugs to the vagina or to the uterus. Specifically, a device such as a tampon, tampon-like device, vaginal ring, pessary, cervical cup, vaginal sponge, intravaginal tablet, or intravaginal suppository, delivers the drug, which can be in the form of a paste, cream, ointment, microcapsule, solution, powder, or gel having a sufficient thickness to maintain prolonged vaginal epithelium and mucosa contact. In one embodiment, the drug can be incorporated into a cream, lotion, foam, paste, ointment, or gel which can be applied to the vagina using an applicator.[1]

In order for the Office to show a *prima facie* case of obviousness, M.P.E.P. §2143 requires that the Office must meet three criteria: (1) the prior art references must teach or suggest all of the claim limitations; (2) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to combine the references, and (3) there must be some reasonable expectation of success. The Office has failed to

[1] D' Augustine et al. at column 18, lines 24-26.

meet its burden under (2) above, as there is no motivation or suggestion to combine the '777 and D' Augustine et al. references to arrive at Applicants' claim 1.

As noted in M.P.E.P. §2142, in establishing obviousness, the Office must show references that teach all of the claimed limitations along with some motivation or suggestion, either in the references themselves or in knowledge generally available to one skilled in the art, to combine the references and arrive at the claimed subject matter.[2] The mere fact that the references can be combined to arrive at the claimed subject matter does not render the resultant combination obvious, unless the prior art also suggests the desirability of the combination. In re Mill, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990). A close reading of the cited references clearly indicates that one skilled in the art would not have been so motivated and, without Applicants' disclosure as a blueprint (which the Office had the benefit of utilizing), such a combination of the '777 and D' Augustine et al. references would not have been made.[3]

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[2]As further set forth in M.P.E.P. §2143.01, obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either explicitly or implicitly in the reference itself, or in the knowledge generally available to one of ordinary skill in the art.

[3]M.P.E.P. §2142 further provides that in order to reach a proper determination under 35 U.S.C. §103(a), the Examiner must step backward in time and into the shoes worn by the hypothetical "person of ordinary skill in the art" when the invention was unknown and just before it was made. Knowledge of Applicants'

The Office asserts that, as the '777 reference teaches benzamide as an effective inhibitor of *Staphylococcus*[4] and D'Augustine discloses effective delivery of desired drugs through non-absorbent vaginal devices, it would have been

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disclosure must be put aside in reaching this determination, yet kept in mind in order to determine the "differences." The tendency to resort to "hindsight" based upon Applicants' disclosure is often difficult to avoid due to the very nature of the examination process. However, as stated by the Federal Circuit, impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art. Grain Processing Corp. v. American-Maize-Products, Co., 840 F.2d 902, 904 (Fed. Cir. 1988).

[4] It is noted that the Office states that the '777 reference discloses benzamide as an inhibitor of *Staphylococcus*. Applicants respectfully note that the '777 reference discloses benzamide as an **antibacterial agent** and not as an inhibitor of *Staphylococcus*. Further, it is worth noting at this time that the first active ingredient used in the exoprotein inhibitor of claim 1 of the present invention is not acting as an antibacterial agent as apparently understood by the Office. As mentioned in Applicants' specification, the first active ingredient acts to **inhibit the production of exoproteins** from Gram positive bacteria, but does not seek to kill the bacteria as the killing of bacteria is non-selective and the "good" bacteria needed to maintain a healthy vagina would also be killed. Thus, the non-selective killing of bacteria could actually be very harmful to the vagina and could cause serious health problems. This is significant. The first active ingredient as claimed in claim 1 of the present invention actually seeks not to act as an antibacterial agent as claimed by the Office, but seeks to only prevent the production of potentially harmful by-products of bacteria, while allowing the bacteria to live. It is also noted that the '777 reference does not suggest or disclose that a composition having the general formula of the first active ingredient of claim 1 can act in such a manner.

obvious for one skilled in the art at the time of the instant invention to add the benzamide of the '777 reference to the non-absorbent devices of D'Augustine for inhibiting bacterial infections in the vaginal area. With all due respect, Applicants submit that this is not a convincing line of reasoning as to why the combination of these references would have been obvious to one skilled in the art at the time of the invention. Specifically, why would one skilled in the art pick the composition of the '777 reference over all of the other non-toxic, antibacterial compositions in the art, particularly when the D'Augustine et al. provide numerous suitable antibacterial compositions to use with their non-absorbent devices and do not point to any need for alternatives?

D' Augustine et al. simply teach compositions that can be used as antibacterials to treat bacterial infections of the vagina and devices for delivering the compositions; and even provide several commercially acceptable antibacterial compositions. The D' Augustine et al. reference fails to provide a reason why one skilled in the art would choose another antibacterial over those listed in the D' Augustine et al. reference or disclosed elsewhere in the art. The '777 reference is directed to improving the bactericidal action of hexachlorophene by combining hexachlorophene with other antibacterial compounds, in one embodiment, with benzamide. No where in the '777 reference is it disclosed to use the antibacterial composition including benzamide for the treatment of vaginal fungal, bacterial, viral, and parasitic infections in and around the vagina. As such, one skilled in the art would

not, and could not, be motivated to use the compounds of '777 over any other antibacterial compounds in the intravaginal devices of D' Augustine et al. to arrive at each and every limitation of Applicants' claim 1.

With all due respect, it appears that the Office has used impermissible hindsight analysis and reconstruction when combining the '777 and D'Augustine, et al. references. There is simply no motivation or suggestion to combine the '777 reference with the D'Augustine reference to arrive at each and every limitation of claim 1.

As there is no motivation or suggestion to combine the '777 and D' Augustine et al. references to arrive at each and every limitation of claim 1, claim 1 is patentable over '777 in view of D'Augustine et al.

Claims 11 and 14-20 depend directly from claim 1. As such, claims 11 and 14-20 are patentable over '777 in view of D'Augustine et al. for the same reasons as claim 1 set forth above, as well as for the additional elements they require.

2. Rejection of Claims 1, 11, 14-20, and 22-31 Under 35 U.S.C. §103(a)

Reconsideration is requested of the rejection of claims 1, 11, 14-20, and 22-31 under 35 U.S.C. §103(a) as being unpatentable over Syverson et al. (U.S. 5,612,045) in view of DE 1204777('777).

Claim 1 is discussed above. Additionally, the '777 reference is discussed above.

As discussed above, '777 fails to disclose a non-absorbent

substrate for insertion into the vagina being selected from the group consisting of a non-absorbent incontinence device, a barrier birth control device, a tampon applicator, and a douche. Additionally, the '777 reference fails to disclose ethers as a second active ingredient as required in claims 22-31. In an attempt to find each and every element of claim 1 and further each and every element of claims 22-31, the Office attempts to combine 5,612,045 ('045) with the '777 reference. Specifically, the Office states that it would have been obvious for one of ordinary skill in the art to combine the benzamide compound of '777 with the toxin inhibiting ether compounds of '045 and apply the compounds to the feminine hygiene products of '045. Furthermore, the Office states that while '045 does not specifically state non-absorbent articles, absent any unexpected results with respect to the non-absorbency of the articles, it would have been within the scope of a skilled artisan to use either non-absorbent or absorbent articles for incorporating the compounds of '777 and '045.

As noted above, a *prima facie* case of obviousness under M.P.E.P. §2143 requires that the Office must meet three criteria: (1) the prior art references must teach or suggest all of the claim limitations; (2) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to combine the references, and (3) there must be some reasonable expectation of success. The Office has failed to meet its burden under (1) and (2) above, as the cited references alone or in combination fail to show an exoprotein inhibitor

comprising a non-absorbent substrate and there is no motivation or suggestion to combine and/or modify the '777 and '045 references to arrive at Applicants' claim 1.

As noted above, neither of the cited references expressly teaches a non-absorbent substrate selected from the group consisting of non-absorbent incontinence device, a barrier birth control device, a tampon applicator, and a douche for use in inhibiting exoprotein production in and around the vagina. While Applicants agree with the Office that the '045 reference teaches absorbent articles including compounds to inhibit exoprotein production, Applicants assert that no where in '045 it is suggested or taught that the same compounds could be used in the same manner on a non-absorbent substrate to inhibit exoprotein production. As such, the Office has not shown a convincing line of reasoning for one skilled in the art to use the compounds of the '045 reference on non-absorbent substrates to inhibit exoprotein production.

Furthermore, even if one skilled in the art, reading '045, would be motivated to use the compounds of '045 on a non-absorbent substrate (which Applicants assert they would not be so motivated), there is no motivation or suggestion to combine the cited references and arrive at each and every limitation of claim 1.

As noted above, '045 simply teach ether compositions that can be used with absorbent articles such as catamenial tampons to inhibit the exoproteins of Gram positive bacteria. Specifically, '045 is directed to solving the problem of toxic shock syndrome, which is caused by TSST-1, an exoprotein

produced by *S. aureus* found in the vagina.[5] Additionally, while the '045 reference generally teaches that the ether compositions may employ additional active materials such as supplementary antimicrobials, anti-parasitic agents, antipruritics, astringents, local anaesthetics, or anti-inflammatory agents[5], the '045 reference fails to provide a reason why one skilled in the art would choose benzamide disclosed in '777 as the additional antibacterial over any of the other numerous antibacterials disclosed elsewhere in the art.

The '777 reference is directed to improving the bactericidal action of hexachlorophene by combining hexachlorophene with other antibacterial compounds, specifically, in one embodiment, with benzamide. No where in the '777 reference is it disclosed to use the antibacterial composition, specifically benzamide, for the inhibition of exoprotein production in and around the vagina. Furthermore, no where is it disclosed in '777 that the antibacterial benzamide would be safe to use internally in humans. As such, one skilled in the art would not, and could not, have been motivated to use the '777 composition on an absorbent substrate such as a catamenial tampon, which would inevitably, and unavoidably, contact the sensitive mucosal membrane of the inner vagina. As such, one skilled in the art would not, and could not, be motivated to use the compounds of '777 over any other

[5] *See* U.S. 5,612,045 at column 2, lines 6-11.

antibacterial compounds in the intravaginal devices of '045.

With all due respect, it appears that the Office has used impermissible hindsight analysis and reconstruction when combining the '045 and '777 references. There is simply no motivation or suggestion to combine the '045 reference with the '777 reference to arrive at each and every limitation of claim 1.

As no where in the cited references, is an exoprotein inhibitor comprising a non-absorbent substrate as required in claim 1 taught or suggested and further, there is no motivation or suggestion to combine the '045 and '777 references to arrive at each and every limitation of claim 1, claim 1 is patentable over '045 in view of '777.

Claims 11, 14-20, and 22-31 depend directly or indirectly from claim 1. As such, claims 11, 14-20, and 22-31 are patentable over '045 in view of '777 for the same reasons as claim 1 set forth above, as well as for the additional elements they require.

3. Rejection of Claims 1, 11, 14-20, and 48-55 Under 35 U.S.C. §103(a)

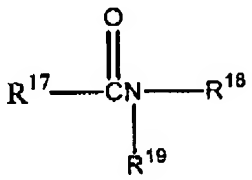
Reconsideration is requested of the rejection of claims 1, 11, 14-20, and 48-55 under 35 U.S.C. §103(a) as being unpatentable over Syverson et al. (U.S. 5,685,872) in view of DE

[6] U.S. 5,612,045 at column 5, lines 23-27.

1204777('777).

Claim 1 is discussed above. Additionally, the '777 reference is discussed above.

As discussed above, '777 fails to disclose a non-absorbent substrate for insertion into the vagina being selected from the group consisting of a non-absorbent incontinence device, a barrier birth control device, a tampon applicator, and a douche. Additionally, the '777 reference fails to disclose active agents having the general formula:



wherein R^{17}, inclusive of the carbonyl carbon, is an alkyl group having 8 to 18 carbon atoms, and R^{18} and R^{19} are independently selected from hydrogen or an alkyl group having from 1 to about 12 carbon atoms which may or may not be substituted with groups selected from ester groups, ether groups, amine groups, hydroxyl groups, carboxyl groups, carboxyl salts, sulfonate groups, sulfonate salts, and mixtures thereof as a second active ingredient as required in claims 48-55. In an attempt to find each and every element of claim 1 and further each and every element of claims 48-55, the Office attempts to combine 5,685,872 ('872) with the '777 reference. Specifically, the Office states that it would have been obvious for one of ordinary skill in the art to combine the benzamide compound of

'777 with the toxin inhibiting compounds of '872 and apply the compounds to the feminine hygiene products of '872. Furthermore, the Office states that while '872 does not specifically state non-absorbent articles, absent any unexpected results with respect to the non-absorbency of the articles, it would have been within the scope of a skilled artisan to use either non-absorbent or absorbent articles for incorporating the compounds of '777 and '872.

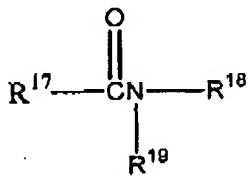
Similar to the arguments made above, the Office has again failed to meet its burden under (1) and (2) of M.P.E.P. §2143 for a *prima facie* case of obviousness, as the cited references alone or in combination fail to show an exoprotein inhibitor comprising a non-absorbent substrate and there is no motivation or suggestion to combine and/or modify the '777 and '872 references to arrive at Applicants' claim 1.

As noted above, neither of the cited references expressly teaches a non-absorbent substrate selected from the group consisting of non-absorbent incontinence device, a barrier birth control device, a tampon applicator, and a douche for use in inhibiting exoprotein production in and around the vagina. While Applicants agree with the Office that the '872 reference teaches absorbent articles including compounds to inhibit exoprotein production, Applicants assert that no where in '872 it is suggested or taught that the same compounds could be used in the same manner on a non-absorbent substrate to inhibit exoprotein production. As such, the Office has not shown a convincing line of reasoning for one skilled in the art to use the compounds of the '872 reference on non-absorbent substrates

to inhibit exoprotein production.

Furthermore, even if one skilled in the art, reading '872, would be motivated to use the compounds of '872 on a non-absorbent substrate (which Applicants assert they would not be so motivated), there is no motivation or suggestion to combine the cited references and arrive at each and every limitation of claim 1.

'872 simply teach nitrogen containing compounds having the general formula:



wherein R^{17}, inclusive of the carbonyl carbon, is an alkyl group having 8 to 18 carbon atoms, and R^{18} and R^{19} are independently selected from hydrogen or an alkyl group having from 1 to about 12 carbon atoms which may or may not be substituted with groups selected from ester groups, ether groups, amine groups, hydroxyl groups, carboxyl groups, carboxyl salts, sulfonate groups, sulfonate salts, and mixtures thereof that can be used with absorbent articles such as catamenial tampons to inhibit the exoproteins of Gram positive bacteria. Specifically, '872 is directed to solving the problem of toxic shock syndrome, which is caused by TSST-1, an exoprotein produced by *S. aureus* found in the vagina.[7] Additionally, while the '872 reference

[7] *See* U.S. 5,685,782 at column 2, lines 7-12.

generally teaches that their nitrogen containing compounds may employ additional active materials such as supplementary antimicrobials, anti-parasitic agents, antipruritics, astringents, local anaesthetics, or anti-inflammatory agents[8], the '872 reference fails to provide a reason why one skilled in the art would choose benzamide disclosed in '777 as the additional antibacterial over any of the other numerous antibacterials disclosed elsewhere in the art.

As noted above, the '777 reference is directed to improving the bactericidal action of hexachlorophene by combining hexachlorophene with other antibacterial compounds, specifically, in one embodiment, with benzamide. No where in the '777 reference is it disclosed to use the antibacterial composition, specifically benzamide, for the inhibition of exoprotein production in and around the vagina. Furthermore, no where is it disclosed in '777 that the antibacterial benzamide would be safe to use internally in humans. As such, one skilled in the art would not, and could not, have been motivated to use the '777 composition on an absorbent substrate such as a catamenial tampon, which would inevitably, and unavoidably, contact the sensitive mucosal membrane of the inner vagina. As such, one skilled in the art would not, and could not, be motivated to use the compounds of '777 over any other antibacterial compounds in the intravaginal devices of '872.

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[8] U.S. 5,685,872 at column 5, lines 36-41.

With all due respect, it appears that the Office has used impermissible hindsight analysis and reconstruction when combining the '872 and '777 references. There is simply no motivation or suggestion to combine the '872 reference with the '777 reference to arrive at each and every limitation of claim 1.

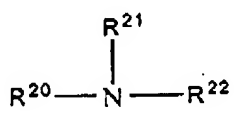
As no where in the cited references, is an exoprotein inhibitor comprising a non-absorbent substrate as required in claim 1 taught or suggested and further, there is no motivation or suggestion to combine the '872 and '777 references to arrive at each and every limitation of claim 1, claim 1 is patentable over '872 in view of '777.

Claims 11, 14-20, and 48-55 depend directly or indirectly from claim 1. As such, claims 11, 14-20, and 48-55 are patentable over '872 in view of '777 for the same reasons as claim 1 set forth above, as well as for the additional elements they require.

4. Rejection of Claims 56-62 Under 35 U.S.C. §103(a)

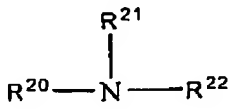
Reconsideration is requested of the rejection of claims 56-62 under 35 U.S.C. §103(a) as being unpatentable over Syverson et al. (U.S. 5,618,554) in view of DE 1204777('777).

Claims 56-62 depend indirectly from claim 1 and further require a second active ingredient having the general formula:



wherein R^{20} is an alkyl group having from about 8 to about 18 carbon atoms and R^{21} and R^{22} are independently selected from the group consisting of hydrogen and alkyl groups having from 1 to about 18 carbon atoms and which can have one or more substitutional moieties selected from the group consisting of hydroxyl, carboxyl, carboxyl salts and imidazoline. Claim 1, which is discussed above, has not been rejected under 103(a) as being unpatentable over 5,618,554 ('554) in view of '777. As such, claims 56-62, which depend from claim 1, are patentable for the same reasons as claim 1, as well as for the additional elements they require.

The '777 reference, which is discussed above, fails to disclose a non-absorbent substrate for insertion into the vagina being selected from the group consisting of a non-absorbent incontinence device, a barrier birth control device, a tampon applicator, and a douche. Additionally, the '777 reference fails to disclose active agents having the general formula:



wherein R^{20} is an alkyl group having from about 8 to about 18 carbon atoms and R^{21} and R^{22} are independently selected from the group consisting of hydrogen and alkyl groups having from 1 to about 18 carbon atoms and which can have one or more

substitutional moieties selected from the group consisting of hydroxyl, carboxyl, carboxyl salts and imidazoline as a second active ingredient as required in claims 56-62. In an attempt to find each and every element of claims 56-62, the Office attempts to combine 5,618,554 ('554) with the '777 reference. Specifically, the Office states that it would have been obvious for one of ordinary skill in the art to combine the benzamide compound of '777 with the toxin inhibiting compounds of '554 and apply the compounds to the feminine hygiene products of '554. Furthermore, the Office states that while '554 does not specifically state non-absorbent articles, absent any unexpected results with respect to the non-absorbency of the articles, it would have been within the scope of a skilled artisan to use either non-absorbent or absorbent articles for incorporating the compounds of '777 and '554.

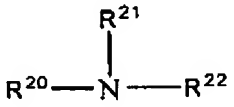
The cited references alone or in combination fail to show an exoprotein inhibitor comprising a non-absorbent substrate and there is no motivation or suggestion to combine and/or modify the '777 and '554 references to arrive at Applicants' claims 56-62. As such, the Office has failed to make a *prima facie* case of obviousness under M.P.E.P. §2143.

As noted above, neither of the cited references expressly teaches a non-absorbent substrate selected from the group consisting of non-absorbent incontinence device, a barrier birth control device, a tampon applicator, and a douche for use in inhibiting exoprotein production in and around the vagina. While Applicants agree with the Office that the '554 reference teaches absorbent articles including compounds to inhibit

exoprotein production, Applicants assert that no where in '554 it is suggested or taught that the same compounds could be used in the same manner on a non-absorbent substrate to inhibit exoprotein production. As such, the Office has not shown a convincing line of reasoning for one skilled in the art to use the compounds of the '554 reference on non-absorbent substrates to inhibit exoprotein production.

Furthermore, even if one skilled in the art, reading '554, would be motivated to use the compounds of '554 on a non-absorbent substrate (which Applicants assert they would not be so motivated), there is no motivation or suggestion to combine the cited references and arrive at each and every limitation of claims 56-62.

'554 simply teach nitrogen containing compounds having the general formula:



wherein R^{20} is an alkyl group having from about 8 to about 18 carbon atoms and R^{21} and R^{22} are independently selected from the group consisting of hydrogen and alkyl groups having from 1 to about 18 carbon atoms and which can have one or more substitutional moieties selected from the group consisting of hydroxyl, carboxyl, carboxyl salts and imidazoline that can be used with absorbent articles such as catamenial tampons to

inhibit the exoproteins of Gram positive bacteria. Specifically, '554 is directed to solving the problem of toxic shock syndrome, which is caused by TSST-1, an exoprotein produced by *S. aureus* found in the vagina.[9] Additionally, while the '554 reference generally teaches that their nitrogen containing compounds may employ additional active materials such as supplementary antimicrobials, anti-parasitic agents, antipruritics, astringents, local anaesthetics, or anti-inflammatory agents[10], the '554 reference fails to provide a reason why one skilled in the art would choose benzamide disclosed in '777 as the additional antibacterial over any of the numerous antibacterials disclosed elsewhere in the art.

As noted above, the '777 reference is directed to improving the bactericidal action of hexachlorophene by combining hexachlorophene with other antibacterial compounds, specifically, in one embodiment, with benzamide. No where in the '777 reference is it disclosed to use the antibacterial composition, specifically benzamide, for the inhibition of exoprotein production in and around the vagina. Furthermore, no where is it disclosed in '777 that the antibacterial benzamide would be safe to use internally in humans. As such, one skilled in the art would not, and could not, have been motivated to use the '777 composition on an absorbent substrate such as a catamenial tampon, which would inevitably, and unavoidably, contact the sensitive mucosal membrane of the inner vagina. As such, one skilled in the art would not, and could not, be

[9] *See* U.S. 5,618,554 at column 2, lines 8-13.

motivated to use the compounds of '777 over any other antibacterial compounds in the intravaginal devices of '554.

With all due respect, it appears that the Office has again used impermissible hindsight analysis and reconstruction when combining the '554 and '777 references. There is simply no motivation or suggestion to combine the '554 reference with the '777 reference to arrive at each and every limitation of claims 56-62.

As no where has the cited references taught or suggested an exoprotein inhibitor comprising a non-absorbent substrate as required in claims 56-62 and further, there is no motivation or suggestion to combine the '554 and '777 references to arrive at each and every limitation of claims 56-62, claims 56-62 are patentable over '554 in view of '777.

In view of the above, Applicants respectfully request favorable reconsideration and allowance of all pending claims. The Commissioner is hereby authorized to charge any fee deficiency in connection with this Letter To Patent And Trademark Office to Deposit Account Number 19-1345 in the name of Senniger Powers.

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[10] U.S. 5,618,554 at column 5, lines 55-60.

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Respectfully Submitted,

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